REMARKS

Claims 1-41 are pending in the application and stand rejected. Claims 2, 4, 10, 13-16, 18-19, 24, 26-28 and 33-39 were indicated as allowable if rewritten in independent form or if amended to overcome the rejections based on formalities.

Drawings

The drawings were objected to under 37 C.F.R. § 1.83(a) for not showing the blocking mechanism breaking the needle body as claimed. Responsive thereto, Applicants have submitted herewith a replacement sheet which includes new FIG. 1 (e). FIG. 1 (e) illustrates the breaking of the needle body. The specification was also amended to describe this figure in two (2) new paragraphs. Antecedent basis for FIG. 1 (e) can be found in Applicants' specification as filed at ¶ [0030], wherein it states that "it is also possible that the blocking mechanism comprises a predetermined breaking point which results in a breaking of the needle body when the lancet system is ejected." Applicants submit that no new matter has been added by new FIG. 1 (e) or the amendments to the specification. In view of newly submitted Fig. 1(e), Applicants respectfully request that the objection to the drawings be withdrawn.

Claim Rejections – 35 U.S.C. § 112

Clams 13, 21, 35 and 38

Claims 13, 21, 35 and 38 were rejected for the claim recitation that "the needle housing 'changes shape' or is 'enlarge[d]' to prevent reuse of the needle." According to the Office Action, this is "subject matter which was not described in the specification . . . ." Office Action, pg. 3. Applicants do not understand this requirement because their specification clearly describes "a change in shape of the needle housing." Applicants' specification, ¶ [0022]. It appears that the Examiner is requiring the needle housing, holding elements thereof and blocking mechanism to be separate and distinct elements with no structural relationship to one another. This need not be the case. The holding elements of the needle housing may be embodied in various forms. In the embodiment of Fig. 1, they are recesses 13, which are clearly part of the needle housing 2a. In the embodiment of Fig. 7, the

holding elements are flexible arms 90 "that are located in the upper portion of the needle housing 35." Id., ¶ [0060]. Since the holding elements are described and illustrated in certain embodiments of Applicants' specification and drawings as part of the needle housing, then the needle housing itself changes shape in such embodiments when the holding element changes shape, just like, e.g., a human body changes shape when its stomach gets larger.

Further, Applicants' specification directly contradicts the Examiner's assertion that "the housing in Figure 7 also does not change shape since the elastic arms (30) move position . . . ." Office Action, pg. 3. To wit, Applicants' specification states that "[w]hen the system is reinserted into a lancing aid the locking arms (90) [i.e., holding elements] are now spread and thus the circumference of the needle housing (2a) is enlarged . . . ." Id., ¶ [0060] (underlining added).

Applicants' specification and drawings clearly support the claim phrase that the needle housing changes shape. Applicants respectfully request that this rejection be withdrawn.

Claims 7 and 9

Claims 7 and 9 were rejected, as Applicants understand it, on the basis that only the embodiment of Fig. 7 is claimed. This is incorrect. Claim 7 recites that the blocking mechanism is actuated when the lancet system is removed from the lancing aid housing. An embodiment incorporating this claimed feature is disclosed in Applicants' specification at ¶ [0052] and Figs. 3a – 3e, which describe and illustrate the blocking mechanism being actuated as the housing 70 is removed from the lancing aid. Claim 9 recites an embodiment in which the blocking mechanism is actuated during a lancing operation. The embodiments disclosed in Figs. 1a-1d and 2a-2d embody this claim. For example, during a lancing operation, the needle body 2b moves from its position shown in Figs. 1a and 1b to the position shown in Figs. 1c and 1d, thereby activating the blocking mechanism. See Applicants' specification, ¶ ¶ [0044] – [0046]. Since claims 7 and 9 are clearly supported by the specification, Applicants' respectfully request that this rejection be withdrawn.

Claim 16

Claim 16 was rejected for the recitation that the blocking mechanism "destroys" the holding element of the lancet system. The Examiner states that "the amended specification does not support this limitation." Office Action, pg. 4. However, the amended specification and the specification as originally filed state that the "blocking mechanism may have a direct or indirect effect on the holding elements . . . at least one holding element is advantageously changed, covered or destroyed . . . ." Applicants' specification, ¶ [0023] (underlining added). In any event, Applicants have amended claim 16 to obviate this issue. Applicants therefore respectfully request that this rejection be withdrawn.

Claims 1, 12 and 34

Claims 1, 12 and 34 were rejected for the recitation of the protective portion and the needle being movable relative to one another. The Examiner requested clarification of these claims elements, which is provided as follows. First, the Examiner correctly acknowledges that the "protective portion" does not refer only to elastomeric protection 4. See Office Action, pg. 5 ("instant amended specification also recites a 'protective portion of the needle housing'"). Thus, to the extent that there is any difficulty in squaring the claim language with the elastomeric protection 4 disclosed in Applicants' specification, such does not create a problem with the claim language because it reads on the protective portion of the needle housing.

The problem arises from the interpretation in the Office Action that claims 1 and 12 "teach the protective portion as separate from the needle housing (the claims two separate components not one as part of the other)." Id. This statement contradicts the language of claim 1, which recites that "the needle housing comprises a protective portion," and claim 12, which recites a "protective portion of the needle housing." Thus, the protective portion is indeed claimed as a part of the needle housing. This claimed feature is fully supported by the specification, which describes a "needle (3) and the plastic body (2b) that is permanently connected thereto are movably mounted in the plastic housing (2a) which represents the protective portion." Applicants' Specification, ¶ [0044] (underlining added). The "protective portion" is thus described and claimed by Applicants as part of the needle housing.

In view of the above clarification, Applicants respectfully request that this rejection be withdrawn.

Claim 10

Claim 10 was rejected for the recitation of the protective portion of the needle housing being transferred to a first position. Responsive thereto, Applicants have amended claim 10, which now comports more closely with the language in independent claim 1 from which claim 10 depends. Applicants respectfully request that the rejection be withdrawn.

Claim 21

Claim 21 was rejected due to the lancing aid not being positively recited. Responsive thereto, Applicants have amended claim 21 to positively recite the lancing aid.

Summary of § 112 Issues

In summary, Applicants have addressed all of the section 112 issues raised in the Office Action by clarifying and pointing to support for specific claim language in the specification and drawings, or by amending the claims. Applicants thus respectfully request that the Examiner withdraw all section 112 rejections.

Claim Rejections – 35 U.S.C. § 103

A. Claims 1, 3, 5-9, 11-12, 17, 20, and 40-41 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Publication No. 2002/0077650 to Schraga ("Schraga II") in view of U.S. Publication No. 2005/0015020 to LeVaughn, et al. ("LeVaughn").

Referring to Fig. 2 of Schraga II, a single use lancet is provided initially in an uncocked and unused position. A user depresses protective cover 40 by grasping knob 42 to cock the lancet, and then pulls off cover 40 as indicated in Fig. 3. After firing, the Schraga II lancet cannot be reused because protrusion 64 engages shoulder 62 as shown in Fig. 4.

LeVaughn has been summarized in previous responses and those summaries are not repeated herein. In the present Office Action, LeVaughn is cited for its protective film 134, which the Examiner asserts qualifies as the claimed protective portion. With reference to

Fig. 13 of LeVaughn, "depressions 124 are preferably covered over by a film 134, which hermetically seals the enclosed space to surrounding the lancet tip 122 to preserve sterility and prevent inadvertent needle-sticks." LeVaughn, ¶ [0106].

The Claims Are Distinguishable Over the Combination of References

First, the combination of references fails to disclose several elements recited in Applicants' claims. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references).

Claim 1 recites a removable lancet system. Similarly, claim 12 recites removal of the lancet system from the lancing aid. The needle body 32 of Schraga II which the Examiner asserts qualifies as the claimed lancet system is not removable from the housing 20. Schraga II discloses a single use device, and as such, actually teaches away from a removable lancet system. See Ormco Corp. v. Align Technology, Inc., 463 F.3d 1299, 1308 (Fed. Cir. 2006) (reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the applicant).

Claims 1 and 12 also specify that the "needle is movably connected to the needle housing." The claim terminology implies that there is a connection between the two components specified and that they are movable relative to one another. The lancet body 32 cited as the claimed "needle housing" and the needle 34 cited as the claimed "needle" of Schraga II appear rigidly fixed together. While Applicants appreciate the Examiner's broad interpretation of their claims, they submit that the claim phrase "movably connected to" does not cover the opposite "rigidly connected to" configuration of Schraga II. Claim 12 has been amended to specify "connected to" rather than "connected with," which comports with the "movably connected to" language already appearing in claim 1.

Claims 1 and 12 also require that the needle housing (as opposed to lancing aid housing) comprises the protective portion. It is unclear where on element 32 (alleged "needle housing" of Schraga II) a skilled artisan could possibly configure a film 134 like that taught by LeVaughn. Even if it could be done, it raises the question of how the needle would

puncture the film, since they would both move together during a puncture. The combination of references thus fails to meet this claim limitation.

Claim 12 further requires that the protective portion of the needle housing is positioned in the first position when the lancet system is removed from the lancing aid. The single use Schraga device prevents removal of the lancet system (element 32) and so this element cannot be met. Further, even if the needle body 32 were removable from the Schraga II housing, the film 134 of LeVaughn that the Examiner wishes to combine with the Schraga II device would still not be positioned in the first position (at least partially surrounding the lancet tip) as claimed because such film would be punctured and the tip would extend through it, as is taught by LeVaughn.

Combining the References Would Destroy the Schraga II Device

The Office Action asserts that it would have been obvious to combine a barrier such as film 134 disclosed by LeVaughn with the device of Schraga, but it does not explain how this would be accomplished. Indeed, if cover 40 of the device of Schraga II were replaced by a film, there would be no means to load the device, i.e., knob 42 that Schraga II discloses to load the lancet would be gone and there would be no handle or other means to load the device. As such, the Examiner's combination would essentially destroy the device of Schraga II for its intended purpose. See In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984) (error to find obviousness where modifying a reference destroys the function or intended purpose of the device disclosed in the reference); In re ICON Health & Fitness, Inc., 496 F.3d 1374, 1382 (Fed. Cir. 2007) ("[A] reference teaches away from a combination when using it in that combination would produce an inoperative result.").

There is No Rational Reason to Combine the Teachings of the References

Further, it does not appear possible to employ a film like film 134 in addition to cover 40 in the Schraga II device because cover 40 leaves no room for an additional film. Further, cover 40 already provides the same function as the film 134, and so a skilled artisan would have no reason or motivation to add this feature. That is, one of skill in the art in pursuit of an improved lancing device would not take the perfectly functional dual purpose (handle and protector) cover 40 of the Schraga II device and replace it with a film and thereby destroy the

device or, on the other hand, add a film to it and duplicate the function of the cover already provided. See KSR International Co. v. Teleflex Inc., 55 U.S. 398, 418 (2007), quoting In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006) ("there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").

Summary of Combination of Schraga II and LeVaughn

In summary, the combination of Schraga II and LeVaughn fails to disclose all of the elements recited in Applicants' independent claims and combining these two references would destroy the Schraga II device for its intended purpose. Applicants thus respectfully submit that independent claims 1 and 12 are non-obvious over the combination of Schraga II and LeVaughn and therefore respectfully request that the rejection be withdrawn. Furthermore, dependent claims 3, 5-9, 11, 17, 20 and 40-41 all depend either directly or indirectly from independent claims 1 or 12 and are thus non-obvious over the combination of references for the same reasons as are claims 1 and 12. Applicants thus respectfully request withdrawal of the rejection of these dependent claims as well.

B. Claims 21-23, 25 and 29-32 were rejected over U.S. Patent No. 5,797,942 to Schraga ("Schraga") in view of U.S. Publication No. 2003/0114839 to Looper, et al. ("Looper").

Schraga discloses a reusable end-cap for use with a hand held lancing device. With reference to Fig. 2, lancet system 60 includes a needle 61 and a removable cap 62. Lancet system 60 is manually inserted into the lancet receiving assembly 120 and the device is cocked by pushing the lancet receiving assembly 120 in the direction of end 117. The cap 62 is removed (and apparently discarded), and the system cap 10 shown in Fig. 3 (or cap 140 shown in Fig. 1) is then placed on body 110, at which point the device is ready to be used for a lancing operation. See Schraga, col. 5, lines 25-35. The lancet 60 has cross-shaped ridges 65 which apparently are received into the zig-zag shaped grooves of body 120, although the purpose of the ridges and grooves is not disclosed in the Schraga patent. The system cap 10 is provided with engagement means 30 that allows the used needle to be held and removed by cap 10, so as to avoid exposure of a used needle with the user. The central teachings of Schraga relate to the use of engagement means 30 of end cap 10 to avoid unnecessary

exposure to a contaminated needle. Compare Figs. 1 and 3; see, e.g., Schraga, col. 2, line 54 – col. 3, line 10.

Looper discloses a surgical instrument assembly 110 (Figs. 2 and 3) that includes a hollow manipulation shaft 120 with a prime mover 130 and an interchangeable surgical tool 160 that connects to the prime mover 130 via a coupler 140, and in particular, to a capture member 150. According to Looper, once the end effector 160 has been utilized and contaminated, a frangible portion 200 such as a notch 210 is distorted or severed to prevent connection. As shown in Fig. 2, the frangible portion 200 is either breakable or distortable to prevent proper coupling to the surgical apparatus. Looper, ¶ [0017].

This combination of references was asserted in the previous Office Action against several other pending claims. Applicants acknowledge with appreciation the Examiner's reconsideration of the issues and partial withdrawal of this rejection. In view of the following discussion, Applicants respectfully request further reconsideration and withdrawal of the remaining claims still standing rejected under the combination of Schraga and Looper.

Independent Claim 21 Is Distinguishable Over the Combination of References

First, claim 21 is distinguishable over the combination of Schraga and Looper. In the previous amendment, claim 21 was amended to recite that the needle is movable to and from the lancing position multiple times after the needle housing is inserted into the lancing aid and before removal therefrom. The Office Action asserts that Schraga discloses this feature at column 9, lines 15-25. This is simply not true. The cited passage discusses the engagement of the cap 10 with the lancet 60 so that the latter can be removed from the lancet receiving assembly. This passage has no disclosure concerning cocking the lancet such that it could be reused without removing the cap.

In fact, Schraga teaches that the cap must be removed from the assembly 110 to cock the needle. Schraga teaches that

> lancet 60 is insertable into the lancet receiving assembly 120, whereupon, the lancet receiving assembly 120 may be pushed in the direction of end 117 within lancet body 110 so as to cock the assembly. At this point, and preferably before, cap member 62 can be twisted off and removed so as to expose the sharp sterile lancet tip 61 and further, the device cap 140 can now be placed on the lancet body 110. Also at this point, the device is ready for use . . . .

Schraga, col. 5, lines 22-30. However, once the cap 10 (or 140) is placed on and connected to the body 110, there is no way to access and push assembly 120 back into the cocked position after the lancet is fired. Schraga makes clear that after the puncture movement the lancet 60 is not returned to a cocked position, but is instead "automatically return[ed] to the intermediate, at-rest orientation within body 110 and cap 140." Id., col. 5, lines 44-48. The cap therefore must be removed to access assembly 120 to perform the cocking procedure described by Schraga. Schraga thus fails to disclose and in fact teaches away from a needle that is movable to and from the lancing position multiple times after the needle housing is inserted into the lancing aid housing and before removal therefrom. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references).

Combining the References Would Destroy the Schraga Device

Claim 21 requires that actuation of the blocking mechanism (1) changes the shape of the needle housing and (2) prevents reuse of the needle with the lancing aid after the needle housing is removed from the lancing aid. The Examiner reads the claimed "needle housing" onto cap 10 of Schraga and the claimed "lancing aid" onto body 110 of Schraga. The Examiner further asserts that it would have been obvious "for the needle housing of Schraga to comprise the blocking mechanism of Looper so that the needle housing of Schraga has a frangible connection with the lancing aid." Office Action, pg. 11.

However, if the cap 10 of Schraga were configured to have a frangible connection with the body 110 as suggested by the Examiner, the cap and/or lancing aid body would be broken after a single use and could not be reused. This would defeat the purpose of the cap 10 of Schraga, which is clearly intended to be connected to and disconnected from the main body 110 every time a used lancet is removed and a new one inserted; i.e., the cap is intended to be reusable. See Schraga, col. 4, lines 58-60. If only the body 110 breaks, the situation is just as bad or worse because the body could then not be re-used.

Either way, configuring the Schraga device with a frangible connection between the cap 10 and main body 110, which the Examiner asserted would be obvious, would destroy this reusable feature and a skilled artisan would therefore avoid it. See In re Gordon, 733

F.2d 900, 902 (Fed. Cir. 1984) (error to find obviousness where modifying a reference destroys the function or intended purpose of the device disclosed in the reference); McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1354 (Fed. Cir. 2001) ("If references taken in combination would produce a 'seemingly inoperable device,' we have held that such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness.")

The Inoperable Schraga Device Still Fails to Meet Claim 21

Additionally, even if a skilled artisan were inclined to modify the device of Schraga so as to destroy the reusable cap feature, the Schraga device so modified still fails to consider Applicants' claim limitations. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references). Namely, actuation of the supposed blocking mechanism of Looper incorporated into the Schraga device would not prevent re-use of the needle after the needle housing is removed from the lancing aid, as is recited in claim 21. While the Examiner's modification undesirably destroys the cap 10, body 110 (or both) of Schraga, it leaves the needle intact. Thus, e.g., a contaminated needle could be released from the Schraga device, not disposed of properly, and then accidentally be reinserted and reused. This problem is addressed in Applicants' specification. See Applicants' specification, ¶4. The Examiner's modified Schraga device thus does not prevent reuse of the needle once the needle housing is removed.

The modified Schraga device would thus suffer a two-fold problem of (1) having a contaminated needle that can be inadvertently re-used after removal from the device and (2) a re-connectable feature between the cap 10 and body 110 that is destroyed.

Summary of Combination of Schraga and Looper

In summary, independent claim 21 is distinguishable over the combination of references and combining the two references would destroy the Schraga device for its intended purpose (i.e., reusable cap). Claim 21 thus cannot be rendered obvious by the combination of Schraga and Looper. In view of the above discussion, Applicants respectfully request that the Examiner withdraw this rejection. Further, since claims 22, 23, 25 and 29-32 depend from claim 21, they are also non-obvious over this combination of

references. Applicants therefore respectfully request that the Examiner withdraw the rejection of these dependent claims.

Allowable Subject Matter

Applicants acknowledge with appreciation the Examiner's indication that claims 2, 4, 10, 13-16, 18-19, 24, 26-28 and 33-39 would be allowable if rewritten or amended to overcome the § 112 rejections. Applicants have amended certain of the claims to address some of the § 112 rejections and have provided clarifying arguments and support in the specification for other claim amendments not being necessary. Applicants respectfully represent that all § 112 issues that have been raised have been addressed and request an indication of allowance of the claims just mentioned.

Furthermore, in view of the arguments above and amendments made to the claims, Applicants submit that the remaining independent and dependent claims are all now allowable. Applicants thus respectfully request allowance of all claims and that this application be passed to issue.

CONCLUSION

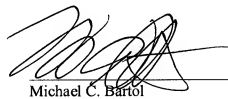
Applicants believe that the foregoing is a complete response to the outstanding Office Action and reconsideration is requested. Specifically, Applicants believe that all claims are now in condition for allowance and allowance thereof is earnestly solicited.

In the event Applicants have overlooked the need for a Petition for Extension of Time or payment of fee (except for Issue Fees), Applicants hereby petition therefor and authorize the United States Patent and Trademark Office to charge any additional fees for extension of time to Deposit Account No. 02-3223, Bose McKinney & Evans LLP.

If the Examiner has any questions regarding any of the foregoing, she is invited to telephone the undersigned at the telephone number listed below.

Respectfully submitted,

BOSE McKINNEY & EVANS LLP



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